

36. The composition according to Claim 32, wherein the one or more pharmaceutically acceptable excipients is selected from the group consisting of lubricants, suspending agents, binders, diluents, flavorants, colorants, dispersing agents and wetting agents.

37. The composition according to Claim 32, wherein the ratio of ergot derivative to hydrophilic swelling agent is about 1:0.5 to about 1:10.

*A! cancel*  
38. The composition according to Claim 32, wherein the ratio of  $\alpha$ -dihydroergocryptine to hydrophilic swelling agent is about 1:0.5 to about 1:5.

39. The composition according to Claim 32, wherein the ratio of bromocriptine to hydrophilic swelling agent is about 1:0.5 to about 1:5.

40. The composition according to Claim 32, wherein the ergot derivative is present in the amount of about 5 to about 80 mg.

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**Remarks**

This Preliminary Amendment is submitted to address issues arising in prosecution of the parent case and place this case in form for allowance.

Claims 1-19 have been cancelled and new Claims 20-40 have been added. Examination of Claims 20-40 is respectfully requested. The new claims submitted in this Preliminary Amendment are supported in the application as originally filed, and Applicant respectfully submits that no new matter is included herein.

In the final Official Action ("Action") in the parent case dated August 1, 2001, Claims 11-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,737,499 to Giger ("Giger") and U.S. Patent No. 5,069, 911 to Züger ("Züger"). Claims 11-19 were rejected under 35 U.S.C. § 102(a) as being unpatentable over Giger and Züger.

The Examiner acknowledges that "none of the cited references specifically disclose a method of improving the bioavailability of ergot derivatives." (Action, page 4) However, the Examiner states that "they all disclose a mixture of an ergot derivative with a hydrophilic

swelling agent and one or more pharmaceutically acceptable excipients." (Action, page 4).

The Examiner also specifically states the following:

The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., bioavailability that is at least 25% higher than conventional drug delivery systems) are not recited in the rejected claim(s).

Action, page 5 (citations omitted).

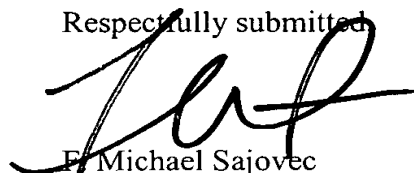
In this Preliminary Amendment, it is respectfully submitted that neither Giger nor Züger, alone or in combination, disclose or suggest the present invention. Moreover, it is respectfully submitted that the present invention is patentable over Giger and Züger, alone or in combination. Applicant directs the Examiner's attention to newly added Claims 20-40 and the declaration under 37 CFR § 1.132 submitted herewith. The investigations described in the declaration provide bioavailability comparison data demonstrating the improved bioavailability of the present invention compared to that of formulations of conventional tablets as well as formulations compared to sustained-release formulations prepared according to the Züger reference. Thus, the present invention is patentable over the cited references.

If any issues remain in this case that would preclude allowance thereof, the Examiner is respectfully requested to contact Applicant's undersigned representative so that a telephonic interview can be arranged.

In re: Mailland  
Serial No.: 10/016,005  
Filed: November 1, 2001  
Page 6

Entry of this Preliminary Amendment, examination of the application, and allowance of all the pending claims is respectfully requested.

Respectfully submitted



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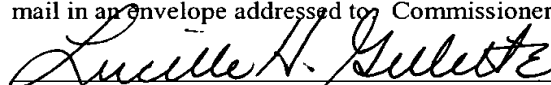


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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, Washington, DC 20231, on March 28, 2002.



Lucille H. Gillette      Date of Signature: March 28, 2002